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## DETAILED ACTION

## **EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Jacqueline D. Wright Bonilla Attorney for Applicant Registration No. 45,239 on 5/25/2010.

## The application has been amended as follows:

In Claim 3 and line 2, the word "essentially" is deleted.

Claim 29 is amended to the following: A composition consisting of a solution of (i) calcitonin at a concentration of about 0.0355% weight/weight; (ii) chlorobutanol at a concentration of equal to or greater than about 0.25% and less than about 0.4% weight/weight; (iii) water; (iv) sodium chloride at a concentration of about 0.85% weight/weight:; and optionally (v) hydrochloric acid; wherein the composition has a pH of 4 or less; and wherein the composition is suitable for intranasal administration in humans.

Claim 30 is amended to the following: A composition consisting of a solution of calcitonin at a concentration of 2200 International Units (I.U.) per ml, chlorobutanol at a concentration of about 0.25% weight/weight, water, sodium chloride at a concentration

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of 0.85% weight/weight, and optionally hydrochloric acid, wherein the composition has a pH of 4 or less, and wherein the composition is suitable for intranasal administration in humans.

## Conclusion

Claims 3-8, 12, 16, 20-30 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to THOMAS S. HEARD whose telephone number is (571)272-2064. The examiner can normally be reached on 9:00 a.m. to 6:30 p.m.. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Thomas S Heard/ Examiner, Art Unit 1654

/Cecilia Tsang/ Supervisory Patent Examiner, Art Unit 1654